

EXHIBIT 4: TORRENT SEARCH TERM LIST

Torrent Search Terms and Search Procedure

Standalone

(*11025* or *18253* or *202223* or *203311* or *203820* or *20473* or *205347* or *20939* or *23491* or *24544* or *24873* or *29392* or *77530* or *78030* or *90483* or *90642* or *90866* or *91235*)
EIR or "establishment inspection report"
OAI or "official action indicated"
"voluntary action indicated"
*diethylamine or "*diethyl amine"
*dimethylamine or "*dimethyl amine"
*dimethylformamide or DMF
*dimethylmethanamide
ghost
NDEA
NDMA
nitra
nitrite
nitrosa
nitroso
NMBA (deferred to after JPML decision)
trosomine
(Form483) or (Form /3 483) or (483 /3 letter) or (483 /3 warn*) or (704 pre/3 b)
C2H6N2O or "(CH3)2NN=O" or "CH32NN=O" or "(CH3)2NC(O)H" or CH32NCOH or C3H7NO or "(CH3CH2)2NH" or CH3CH22NH or C4H11N or "(CH3)2NH" or CH32NH or C2H7N or "(C2H5)2NNO" or C2H52NNO or C4H10N2O
carcin*
deviat* /5 cancer* or deviat* /5 toxic or or deviat* /5 hazard* or deviat* /5 fatal
FDA /10 warning
gene* /3 mutat*
genotoxic*

<term> (no modifiers)^

^Except if run against custodians in management over more than one facility, in which case to be run as indicated in agreed to procedure.

solvent /5 cancer* or solvent /5 toxic or or solvent /5 hazard* or solvent /5 fatal
solvent* /5 contamin*
(test* /5 canc*) AND (<Drug Name> OR <Solvents> AND NOT <other drug names>))
tetrazol*
Valisure*

ADD FOR LOSARTAN
 17599 OR *18153* OR*13668-113* OR *13668-115* OR *13668-409* OR 13668-117* OR *13668-116* OR *13668- 118*
pyrrolidone
butyric
amino
 NMBA

Authors or Inspectors

Last Name	First Name
Agrawal	Atul
Akhtar	Saleem
Amin	Pankaj
Arasu	
Arista	
Arroyo	
Baker	Peter
Barreto	
Barrowcliff	
Bellamy	
Bernard	Tonia
Bizjak	
Boyd	Justin
Bretz	Paula
Brown	Darren
Cartwright	
Casale	
Chapman	Johnathan
Charity	Antony
Chester	Bonita
Clausen	
Cosgrove	
Cruz	
Dezan	
Dickinson	Gwyn
Dobbin	
Dombrowski	
Donald	Steven
Dong	Eric

**Last Name Standalone
UNLESS IF First Name
Exists, THEN (Last
Name /3 First Name) OR
(Last Name AND
<Regulatory Modifiers>)**

Eban	
Ernst	
Estrella	Maria
Etminan	
Ford	Susanna
Frazier	Laurie
Gavini	
George	Jogy
Ghoshal	Rabin
Gidado	
Goga	
Goga	Michael
Hall	Patrice
Hallas	
Harouaka	
Hebert or Della or Dellareese	
Hicks	Kellia
Higgins	Brooke
Huaren	
Hustedt	
Johansen	
Jones	Latoria
Karapetyan*	
Khan	Farhana
Khurana	Sangeeta
Kristensen	
Lopez Rubet	
Maldonado	
Mankind	
Mansournia	
Marcisin	
Martinez	Miguel
Mason	James
Mathew or Mathews	Lata
Mayasandra	Pal
Melende	
Min	Ko
Mistler	
Motamed	
Motta	
Mueller	
Narula	

Navas	
Nguyen	Truong
Oladimeji	
Panicker	
Patel	Nayan
Philopoulos	
Pitts	Simone
Podaralla	Satheesk
Pottgard	
Priester	
Pyramides	
Quartarolo	
Ray	Marcus
Razzaghi	Frederick
Roberts	Daniel
Roy	Melissa
Schwartz	Paul
Shah	Dipesh
Skanchy	
Srivasta	
Srivastava	Rajiv
Stieg	
Sweeney	
Szestypalow	
Tomasso	
Ulysse	
Upadhyay	Pratik
Verdel	
Wakijira	Chaltu
Wang	Zhao
Warnick	
Xu	Atul
Young	Rochelle
Yuscus	
Zaklady	
Zamil	
Zamperini	
Zhen Zhou	

**LOSARTAN INSPECTORS
TORRENT & HETERO**
Last Name

Adams

First Name

Jennifer

Crua	
Djamlee	
George	Jogy
Guardia	
Guerlain	
Harouaka	
Jones	Latorie
Love	Debra
Mathew	Lata
Motamed	Massoud
Namael	Gam
Nguyen	Doan
Shields	Anastasia
Shrivastava	
Smith	Kevin
Smithe	Elyse

Regulatory

("adverse event*" or AER) and (<drug name> or <solvents> or <facility names>)
"changes being effected"
"prior approval supplement"
adulterat*
alert*
CAPA or corrective pre/3 "preventive action"
CFR or eCFR or "code of federal regulations" or USC or "United States Code" or "Title 21"
Citizen* pre/3 Petition
(Establishment pre/3 Inspection)
import* /3 (ban or alert or restrict*)
inadequat*
inspect*
investigat*
major /3 change
(master /3 file) and (<drug name> or <solvents>)
minor /3 change
moderate /3 change
Monthly /3 update
(official pre/3 action* /4 indicat*)
observation*
OOS or "out of spec*" or "out-of-spec"
OOT or "out-of-trend" or "out of trend"
PADER* and (<drug name> or <solvents> or <facility names>)
VAI or (voluntary pre/3 action* /4 indicat*)
violat*
warn*

<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <regulatory modifiers> OR <facility names>)

LOSARTAN ADDITIONS
("320-17-46" OR "320-20-03" OR "320-17-46")
"alternative API"
"FMECA" OR "FMA"
(critical* /25 change* or critical /25 devia* OR critical /25 observ*)
(error* /25 human)OR (error /25 instrument*) OR (error /25 manufactur*) OR (error /25 laboratory) or (error /25 method)
("root cause" /50 analysis) OR ("root cause" /50 *determine*) OR ("root cause" /50 establish*)
"ICH Pharmaceutical Quality System"
"Controlling Nitrosamine Impurities in Human Drugs: Guidance for Industry"
ICSR or "Individual Case Safety Report"

cGMP

(bottle pre/2 lies) or Eban
bury or burie* or conceal*
cGMP* or (current pre/5 manufacturing) or GMP*
"cover up*" or coverup* or "cover-up"
crash* or disaster*
data /4 integrity or data /4 reliabl*
delet* or destroy* or remov* or trash* or shred*
hide* or suppress*
whistleblow*

<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <regulatory modifiers> OR <inspect> OR <manufacturing modifiers> OR <medical modifiers> OR <facility names>)

ADD cGMP for Losartan
"cGMP" or "GNP" /100 *conform*
consult* / 100 ("Meridian" OR retrospec* OR investigat* OR review* OR "MGR Pharma" cGMP OR audit)
"ICH Pharmaceutical Quality System"
"Controlling Nitrosamine Impurities in Human Drugs" or "Guidance for Industry"

QA Testing

"anion-exchange" or anionexchange or "anion exchange"
"ion-exchange" or ionexchange or "ion exchange"
PCRC
aberran*
abnorm*
ALS
bioequiv*
CAPA or corrective pre/5 action
Chromato*
complain*
contami*
degradant* or impurit*
detect*
EI-MS or EL-MS or "electron ionization"
elude*
fail*
fatal*
GC or "GC-FID" or GCMS or "GC-MS"
hazard*
headspace
heat
HPLC-UV
HS
incomplet* /5 data*
LCMS
mass spectro*
method /5 qualification
noise*
noti* w/5 pharm*
obscure*
observation*

<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <manufacturing modifiers>)

peak*
press /4 release
preventative /5 action
problem*
puri*
quality
recall*
repe* /4 error*
residu*
retrospec*
risk*
signal*
spectro*
spike*
suitab*
toxic*
unknown* or unk or unks
validat*

ADD FOR LOSARTAN
skip /50 test*
GAP /10 assessment*
reduce /10 test*
(NIR / 50 (analy* OR implement* OR protocol OR CFR)
GC or "GC-FID" or GCMS or "GC-MS"
poten* /100 HCTZ or poten* /50 assay

Manufacturing

"PROCESS I" or "PROCESS II"
assay*
assessment*
batch /5 records
biocompat*
byproduct*
CAPA or corrective pre/3 "preventive action"
certificat*
change* /3 control*
change* /5 process*
COA or certificat* pre/3 analys*
concentra*
condensa*
conversion*
critical /4 change
crude*
deviat*
diastereo*
discrepanc*
error*
esterficat*
expir*
formaldehyde
malfunct*
material* /3 loss*
moiety or moieties
process /5 change
quench*
reagent*
reclaim*
recover*
recycl*
repack* or "re-pack*"
resal*
resell*

<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))

reuse*
ring*
solvent*
suppress*
TEA or Triethyl*
temperature
TIN or Tributyl*
yield*

ADD FOR LOSARTAN

"carry over" OR "carryover" OR "carry-over"
"change over" OR "change-over" OR "changeover"
"cross contami*" OR "cross-contami*"
"MACO"
abort
contract /10 with OR /10 agreement
hold / 10 time
optimi
patch /20 losartan or /20 batch* /20 product* or /20 pill* or /20 tablet* or /20 finished
potash
reconc
secondary
soda
tertiary
vendor w/25 solvent OR /25 API
alternate* OR "alternate API"
FRE I* OR FRE-II* OR FRE-III* OR FRE-IV* OR FRE-V* OR Stage I* OR Stage II* OR Stage III* OR Stage IV* OR Stage V*
granu*
inject*
lubric*
outsources* OR out-source OR out source
potent*
powder*
homogen

Medical Conditions

bladder*
blood*
cancer* or precancer* or pre-cancer*
colon*
death* or dead or fatal
esophag*
gastro*
intestin*
kidn* or renal*
laten*
leukemia*
liver*
lymphoma*
muta*
myeloma*
NHL or non-hodgkin*
toxicolog*
onset*
oncolog*
ovar*
pancrea*
prostate*
stomach*

**<Term> AND (<Drug
Name> OR (<Solvents>
AND NOT <other drug
names>))**

Economic Terms

AWP or "average wholesale price" or WAC or "wholesale acquisition cost"
best /3 pric*
bulk /3 suppl*
impairment
IRR
manufactur* /3 cost*
marginal /5 cost*
market* /5 share*
net /5 profit*
net /5 valu*
NPA
NPV
rate /10 return
rebate*
sourc* w/5 agree* or sourc* w/5 anal* or sourc* w/5 contract* or sourc* w/5 forecast* or sourc* w/5 plan* or sourc* w/5 strat*
suppl* w/5 agree* or suppl* w/5 anal* or suppl* w/5 contract* or suppl* w/5 forecast* or suppl* w/5 plan* or suppl* w/5 strat*
SWOT or (strength pre/7 threat*)
writ* pre/5 off
(ABDC or Amerisource* or "American Health Packaging" or AHP) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)

<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))

(AG) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or gross or gross or loss)
(amerisource*) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(ANDA) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(ASB) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(Authorized /4 generic) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share)
(average or avg) AND (pric* or cost* or margin* or profit* or revenue*)
(avg) AND (pric* or cost* or margin* or profit* or revenue*)
(boehringer ingelheim) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(cardinal) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(contract) AND (distrib* or PBM)
(cost*) AND (analy* or forecast* or plan* or strat*)
(CVS*) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(Epic) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(ESI) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(Express*) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(IMS) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or loss)

(IQVIA) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or loss)
(Kroger) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(mckesson) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(operat* w/5 margin*) AND (margin* or profit*)
(Optum*) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(pric*) AND (decreas* or increas* or list* or strat* or expect* or project*)
(recall) AND (loss or impairm* or write* or reimburs* or indemn* or charg* or replace*)
(Redoak) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(retail) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or loss)
(Rite*) AND (pric*)
(sales) /5 (expect* or project*)
(var*) /5 (cost*)
(variable) /5 (cost*)
(Walgreen* or WBDA) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(Walmart) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)

Entities

Alembic
ABDC or Amerisource* or "American Health Packaging" or AHP
Amerigen
ANDA
Auro* or APL or APUSA
boehringer ingelheim
Bristol
Camber
Cobalt
distribut*
Forest
Hetero
Huahai
Indoco
Ivax
Jubilant
Lantech*
Macleod*
Matrix
Mylan
Novartis
Par
Prinston
Qualanex
Ranbaxy
Sandoz
Syncore
Synthon
Teva
Torrent
Unichem

**<Term> AND (<Drug
Name> OR (<Solvents>
AND NOT <other drug
names>))**

Watson	
Zhejiang*	
ZHP	
ADD FOR LOSARTAN	
ABC	
Blupaz	
EconDISC	
H D Smith	
Masters	
Harvard	
RxSS	
PBA GCP	
RS Northeast	
Arrow	
Granule	

Drug Names

Valsartan
amlodipine*
Diovan*
Exforg*
HCT or HCTZ
sartan or sartans

<drug names modifiers>

Losartan or Losartan Potassium
Losartan HCTZ or Losartan Potassium HCTZ
Cozaar
Hyzaar
Losartan K

Solvents

azide
formaldehyde
-N3
xylene
acid*
aqueous*
chloramin*
HNO2
hydrochlor*
N-3*
NaNO*
tolue*
Tributyl* or TIN
Triethyl* or TEA
zinc /3 chloride
ZnCl*

<solvents modifiers>

ADD FOR LOSARTAN
acetone
alcohol
Isopropyl
methenol
KOH
carbon*
ammonium bromide
sodium borohydride
pyrrolid one

Regulatory

"Abbreviated New Drug Application" or ANDA
CDC or "Centers for Disease Control"
CDER or "Center for Drug Evaluation and Research"
DEA or "Drug Enforcement Administration" or "Drug Enforcement Agency"
"Environmental Protection Agency" or EPA or USEPA or "US-EPA" or "1200 Pennsylvania Avenue"
"Food and Drug Administration" or FDA or USFDA or "US-FDA" or "College Park"
NIH or "National Institutes of Health"

<regulatory modifiers>

LOSARTAN ADDITIONS
"FMECA" OR "FMA"
"ICH Pharmaceutical Quality System"
"Controlling Nitrosamine Impurities in Human Drugs" or "Guidance for Industry"
ICSR or "Individual Case Safety Report"

Inspect

Agency
inspect*
regulat*

<inspect modifiers>

Manufacturing

backup /3 data
impurit* and degradant*
recall*
residu*
solvent*
spike*
test*
unknown /3 peak or unknown /3 spike or unknown /3 impurit* or unknown /3 contamin*

<manufacturing modifiers>

ADD FOR LOSARTAN

"carry over" OR "carryover" OR "carry-over"
"change over" OR "change-over" OR "changeover"
"cross contami*" OR "cross-contami*"
"MACO"
abort
contract /10 with OR /10 agreement
hold / 10 time
optimi
patch
potash
reconc
secondary
soda
tertiary
vendor
alternate* OR "alternate API"
FRE* OR stage*
granu*
inject*
lubric*

outsourc* OR out-sourc* OR out sourc*
potent*
powder*
homogen

Medical Conditions

"adverse event*" or AER*
bladder*
blood*
cancer* or precancer* or pre-cancer*
colon*
death* or dead or fatal
esophag*
gastro*
intestin*
kidn* or renal*
laten*
leukemia*
liver*
lymphoma*
MedWatch* or "Safety Information and Adverse Event Reporting"
muta*
myeloma*
NHL or non-hodgkin*
toxicolog*
onset*
oncolog*
ovar*
PADER*
pancrea*
prostate*
stomach*

**<medical conditions
modifiers>**

Economic Terms

analys*
AWP
cost*
decreas*
distrib*
expect*
gross
impairm*
increas*
indem*
list*
loss*
margin*
market*
net
PBM
plan
pric*
profit*
project*
recall*
revenue*
share*
stock*
strat*
WAC
write*

<economic modifiers>

Facility Names

LOSARTAN
FEI-3007078804
FEI-3005029956
FEI-3009093782
FEI-3005430968
FEI-3002246664
Torrent Indrad
Torrent Dahej
Hetero
Cadila
Teva

Foreign Regulatory Agencies

ABPI
AEMPS
Agency /3 Therapeutic
AIFA
ALIMS
ANMAT
BDA
BfArM
"British Pharmaceutical Industry"
"Bulgarian Drug Agency"
Canad* /3 Health
"Central drugs standard control"
CEP
DKMA
EMA
European /3 medic*
"European Medical"
Fimea
"Health Canada"
Health* /5 Agency
Hong Kong /7 "Drug Office"
HPRA
IMA
MEB
Medical /4 agency
"Medical Products Agency"
MFDS
MHRA
Ministry /3 Health
Ministry /5 drug
MPA
NAMMD
NHS
NIHS
NoMA

**<foreign regulatory agency
modifiers>**

NPRA
OGYEI
PHARMAC
SAMLV
SAMR
SCMA
SIDC
"State Administration for Market"
SUKL
Swissmedic
TGA
"Therapeutic Goods Administration"

SEARCH TERMS PROCEDURE

1. Search Terms

The Primary Search Terms and Modifiers lists attached hereto as Exhibits A and B shall be used for searching of custodial records subject to the procedure set forth herein.

As there are several custodians who will be included in losartan discovery who were already custodians during valsartan discovery, the procedure for running terms for them will differ from those employees who are first-time losartan custodians. Those custodians whose files were produced during the valsartan portion of the case shall be referred to as the "Original Custodians." For the former, Torrent will top up the custodial files to reflect the newly agreed upon Relevant Time Period. Torrent will then run the new set of search terms over the Original Custodians' files, deduplicate documents for those which have already been produced, and produce any previously unproduced files. To the extent a duplicate document is not produced but is located in the custodial file of a different custodian, Torrent will produce an overlay production that adds those custodians to the documents at issue.

For the new custodians, the search will be run in full in accordance with the agreed upon set of search terms in this document.

2. Standalone Terms

a) The following terms shall remain on the standalone terms list but can be tested and

refined further if a need is shown after documents are collected and preliminarily reviewed:

- i. *diethylamine or "*diethyl amine"
- ii. *dimethylamine or "*dimethyl amine"
- iii. *dimethylformamide or DMF
- iv. *dimethylmethanamide
- v. *ghost*

- vi. *NDEA*
- vii. *NDMA*
- viii. *NMBA*
- viii. *nitra*
- ix. *nitrite*
- x. *nitrosa*
- xi. *nitroso*
- xii. *trosomine*
- xiii. C₂H₆N₂O or "(CH₃)₂NN=O" or "CH₃2NN=O" or "(CH₃)₂NC(O)H" or CH₃2NCOH or C₃H₇NO or "(CH₃CH₂)₂NH" or CH₃CH₂2NH or C₄H₁₁N or "(CH₃)₂NH" or CH₃2NH or C₂H₇N or "(C₂H₅)₂NNO" or C₂H₅2NNO or C₄H₁₀N₂O
- xiv. tetrazol*
- xv. gene* /3 mutat*
- xvi. genotoxic*
- xvii. carcin* (but may modify if needed)
- xviii. deviat* /5 cancer* or deviat* /5 toxic or deviat* /5 hazard* or deviat* /5
fatal (but may modify if needed)
- xix. FDA /10 warning (but may modify if needed)
- xx. solvent /5 cancer* or solvent /5 toxic or solvent /5 hazard* or solvent /5 fatal (but may modify if needed)
- xxi. solvent* /5 contamin* (but may modify if needed)
- xxii. Valisure* (but may modify if Valisure comes up for a reason other than its role in relation to detecting nitrosamines).